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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,938	10/20/2000	James L. Meyerhoff	Army 126	6469

7590 10/22/2002

Caroline Nash
Nash & Titus LLC
3415 Brookeville Rd
Brookville, MD 20833

EXAMINER
GUPTA, ANISH

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/692,938	MEYERHOFF ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5 and 7-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 7-12* is/are rejected.

7)☒ Claim(s) *3 and 5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The amendment filed 7-16-02 has been full acknowledged. Claims 2, 4 and 6 were canceled, claims 1, 3, 5, 7, 10 were amended and claim 13 was added. Claims 1, 3, 5, 7-13 are pending in this application.

Claim Rejections - 35 USC § 112

2. The rejection of claims 1-12, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 7-12 remain and newly added claim 13 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment ischemia, does not reasonably provide enablement for the treatment or prevention of other neurological and neurobehavioral disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to enable the invention commensurate in scope with these claims for the reasons set forth in the previous office action and the reasons set forth below.

Applicants argue that new art does not accord with Patel's assertion. Unlike TRH, the pGlu-Glu-Pro-amide peptide is not attacked by thyroliberinase and does not enter the brain.

Applicants state that "[t]he fact that p-Glu-Glu-Pro-amide enters the brain more readily than does TRH and is superior to TRH in neuroprotective capacity (Koenig et al., 2001) should be entirely persuasive to one skilled in the art that it specifically would be therapeutically beneficial in attenuating the progression of and ameliorating symptoms of chronic neurodegenerative diseases affecting the CNS, such as AD, Parkinson's Disease (PD), age-related macular degeneration (AMD) and amyotrophic lateral sclerosis (ALS)." Applicants also stated "[w]hile not ruling out that pGlu-Glu-Pro-amide might exert a trophic effect enhancing neural regeneration or connectivity, the Applicants have not make that specific claim at this juncture."

First, it should be noted that all of the references relied upon by in their arguments have not been properly cited on a 1449 and thus have not been considered.

Applicants' arguments with regard to the treatment of AD, PD, AMD, or ALS are entirely speculative. Applicants stated that even Patel states that "TRH exters a positive neuromodulatory effect on the cholinergic system." Even with these results, the reference nevertheless concludes which teach that Alzheimer's disease is known to be difficult to treat and that there is neither a clear understanding of the origin and pathophysiology of the disease no an animal model of illness (see page 81). Applicants' citations of various references (those which have not been cited on a 1449) do not clearly establish that the tri-peptide would be effective in the treatment of AD, PD, AMD, or ALS. It remains unclear how one of ordinary skill in the art can conclude that since the tripeptide is a neuroprotectant it can be used to treat AD, PD, AMD, or ALS conclusively. It has not been argued that the tri-peptide have neuroprotectant ability. Note that the rejection

conceded that the peptide was effective in the treatment of ischemia. However, in the instant specification, there is very little guidance provided in the way of working examples that the claimed compounds would be effective in the treatment of Alzheimer's, ALS or Parkinson's or other similar disorders.

Finally, Applicants have not addressed any issues with regards to prevention of said disease and as to the regeneration of neurons, Applicants claims are broad enough to encompass this mode of treatment. Although Applicants may not have the intent to claim this mode of treatment, the claims are broad enough to encompass as such.

Rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 remains rejected under 35 U.S.C. 102(b) as being anticipated by Cremades et al. for the reasons set forth in the previous office action and the reasons set forth below.

The claims are drawn to a pharmaceutical formulation comprising pGlu-glu-Pro-NH2.

Applicants argue the reference "teaches nothing about the capacity of pGlu-Glu-Pro-amide to reach or affect the central nervous system." Applicants argue about the lack of the guidance provided in the reference to reach the blood/brain barrier.

Applicant's arguments filed 7-16-02 have been fully considered but they are not persuasive.

The claims are drawn to a pharmaceutical formulation. The amended claim language of neuroprotectant is intended use language. Intended use limitation and intended use or field of use for the invention generally will not limit the scope of a claim. Moreover, where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, supra.

6. Claims 3 and 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda , can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta 1/13/02

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600